GUIDANT

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Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services,
Food and Drug Administration
5630 Fishers Lane, Room 1061, (HFA-305)
Rockville, MD 20852

Subject: Comments on FDA's Draft Guidance, "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme"
Docket No. 99N-4491

Dear Sir or Madam:

Enclosed are the comments from Guidant Vascular Intervention concerning FDA's Draft Guidance, "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme".

Guidant Corporation develops and manufactures medical devices to provide physicians and patients with leading edge technologies for improved patient care and clinical outcomes. Guidant's primary concern in developing innovative products is patient safety. Through the product development process, Guidant ensures products perform both safely and effectively for their labeled intended use through extensive and rigorous product testing and validation. These data support whether the product is labeled for single or for multiple-use. Patient safety is paramount and ensuring that Guidant devices are used as labeled is in the best interest of both our patients and physician customers in supporting positive clinical outcomes.

Guidant products labeled as single-use only devices have been tested and validated to support this claim. These devices have not been validated after being subjected to cleaning and resterilization processes, and as such Guidant cannot ensure that the product will continue to be safe and effective for multiple use. Validating a device for reuse involves many variables and combinations that cannot be adequately and safely addressed in FDA's proposed flowcharts in their draft guidance document. Evaluating all of these factors provides a challenge in predicting all variables each reused device will encounter. Evaluating the additional patient risks of potential infection and device performance including the cumulative effects of clinical usage, patient anatomy, cleaning and resterilization would be a challenge to simulate in an adequate product validation and difficult to thoroughly assess through the use of both risk evaluation flowcharts included in this draft proposal.

The evaluation and categorization of risk associated with device reuse and reprocessing needs to be based on the accumulation and analysis of scientific data. These data need to

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be accumulated and reviewed by FDA prior to the categorization of medical devices into FDA's proposed risk based categorization scheme. Scientific data need to be available to determine the risks associated with the specific device and the effects, if any, of the process of reprocessing on the safety and effectiveness of medical devices. These data need to be available prior to the determination of the medical device categorization into an appropriate risk level. Additionally, these data to support the proper classification of devices into risk-based categories need to be available prior to the implementation of this draft guidance document.

Respectfully Submitted,

Sandra Sundell

Sandra Sundell
Manager, Regulatory Affairs

Enc.

Comments on Draft Guidance

The Food and Drug Administration's implementation of a new Review Prioritization Scheme as outlined in the current draft guidance document, "Reprocessing and Reuse of Single-use Devices: Review Prioritization Scheme," is in direct contrast to the responsibilities outlined for FDA in the Food Drug & Cosmetic Act (FD&C Act). Reuse of single-use only devices (SUD) consists of cleaning, disinfecting and resterilizing and reusing medical devices, originally labeled by the original equipment manufacturer (OEM) for single-use only. Medical devices are labeled as single-use only devices through extensive product development processes including extensive and rigorous product testing and validations to ensure these products perform both safely and effectively for their labeled intended use. These data directly support whether the product is labeled for single or for multiple-use, determining the intended use of the device. Reuse of devices labeled for single-use only raises concerns regarding patient safety, informed consent and equitable regulation of reuse under the FD&C Act.

FDA's current regulations include a risk based categorization scheme. The FDA proposed draft guidance outlines a new risk based prioritization system for determining the risk category of reprocessing medical devices labeled for single-use only, but this system is based on working through a flowchart and answering questions, and in essence is based upon individual interpretation, not based on data. Reprocessed device data are needed for every device subjected to this new scheme to support the appropriate categorization of these devices. Other product performance characteristics outlined in the flowchart are subjective including device design, materials, design changes and modifications, coatings, compatibility with multiple sterilization methods, multiple sterilization cycles and the compatibility of materials and designs with various cleaning methods. All of these factors need to be addressed and supported with scientific data, not individual interpretation.

FDA does not ordinarily address risks associated with potential reprocessing of SUDs because as stated in the FD&C Act §513(i)(1)(E)(i) their determination is limited to the proposed labeling submitted in a report for the device under premarket notification regulations. FDA's regulatory authority over the intended use of a device is limited to the sponsor's proposed labeling. FDA should follow its charter outlined in the FD&C Act. FDA needs to enforce its own regulations and fulfill its responsibility under the FD&C Act to protect the public health through universal enforcement of the existing 510(k) and premarket approval regulations.

Flowchart 1 – Infection Risk

FDA's flow chart outlining the prioritization scheme for evaluating the risk of infection when determining the risk categorization of a medical devices labeled for single-use only for reprocessing is inadequate for ensuring patient safety. This system is based on working through the flowchart and answering questions, in essence is entirely based upon subjective evaluation, not based on data. The risks associated with an invasive medical device not being sterile are unacceptable risks to patient safety. Question 2 in the flowchart bases the decision making process on the presence or absence of post market data. With the current lack of post-market data available, one cannot adequately assess the increased risk of infection due to inadequate or improper cleaning, inadequate sterilization or increased patient exposure to bacterial endotoxins. The absence of post-market data does not necessarily imply that there is not an increased risk of infection with the use of a reprocessed device. Question 3 asks one to determine if the SUD includes features that could impede adequate cleaning and resterilization. In making a proper determination of this risk one would need to be familiar with the design, materials and processing of the individual device. The OEM has already evaluated the device through the product development process and labeled the device appropriately as single-use only. Without knowledge of the device specifications, design, and product validation, a proper determination of a device's reuse characteristics cannot adequately be determined. This includes an increase in the risk of successfully decontaminating certain polymeric materials in devices with complex geometry and small lumens. In the case of improper and/or inadequate cleaning of these devices, there is the potential to prevent adequate penetration of the subsequent sterilant, thus rendering the sterilization ineffective. Resterilization processes need to address material compatibilities with the sterilization method, the operating parameters of the resterilization processes and how these affect product performance. The physical and chemical effects of both the cleaning and sterilization processes associated with reprocessing have the potential to cause the device to not perform as intended. The increasing use of advanced materials with high stress and heat sensitive properties as well as the use of product enhancing coatings can be affected by the cleaning and sterilization methods of the reprocessing process. Reprocessing also eliminates the benefit of the product attribute associated with the coating. Additionally, "wiping down" of devices as part of many resterilization processes will add unknown stresses to sensitive catheter components and may cause damage that will not be noticed until the product is reused. Question 4 enables risk to be determined based on an assumption that a reusable device exists that has an equivalent design and intended use as the SUD. This equivalency determination should not be based on subjectivity and cannot be adequately made without supporting data.

The agency also needs to consider the historical risks associated with reused devices including patient safety and increased risk of infection, sterilization method compatibility and sterilization validation methods, contamination due to bacterial endotoxins and the difficulty of tracing patient infections with long incubation periods back to the source of infection.

Flowchart 2 – Inadequate Performance Risk

FDA's flow chart outlining a method for evaluating the risk of product performance when reprocessing medical devices labeled for single-use only is also inadequate to ensure patient safety. This system is based on working through the flowchart and answering questions, in essence is also based upon subjective evaluation, not based on data.

Guidant products labeled as single–use only devices have been tested and validated to support this claim. These devices have not been validated after being subjected to cleaning and resterilization processes, and as such Guidant cannot ensure that the product will continue to be safe and effective for multiple use. Question 1 in the flowchart bases the decision making process on the presence or absence of post market data. With the current lack of post-market data available, one cannot adequately assess the increased risk of injury when compared to the use of an SUD that has not been reprocessed. The absence of post-market data does not necessarily imply that there is not an increased risk of patient injury with the use of a reprocessed device.

When validating a device such as a balloon dilatation catheter for reuse, the following variables should be considered at a minimum, including the clinical procedure, the decontamination process, the resterilization process and the actual device performance. Additionally, considerations to ensure and/or prove the safety of the device for re-use will include variables such as the number of balloon inflations performed, balloon pressures, duration of balloon inflation and patient anatomy, specifically vessel tortuosity, lesion classification and degree of calcification. The cumulative effects of stress in re-use will vary with clinical scenarios and may be difficult to simulate in an experimental situation. Decontamination processes vary in types of cleaning agents, temperatures employed, duration of the cleaning cycle, and the effects of the cleaning process on material degradation and device coatings. A dilatation device that was not adequately cleaned could have reduced functional performance that could jeopardize patient safety. For example, residual contrast in the inflation lumen of a device could result in an increase in the balloon deflation time.

Evaluating all of the factors discussed above in the design of a validation for balloon reuse provides a challenge since one cannot predict all variables each reused balloon will encounter. There is also market pressure to develop new materials with enhanced initial performance, but these materials may have poor reuse characteristics. This in addition to the cumulative effects of clinical usage, cleaning and resterilization would be difficult to simulate in an adequate product validation, and cannot be adequately determined through the draft flowcharts.

For reasons stated previously, OEMs even with the use of these draft flowcharts cannot anticipate all of the risks associated with reprocessing as the risks will vary with the type of product usage, patient anatomy, the type of sterilization, the number of

resterilizations, etc. If OEMs cannot predict these additional risks, how is the risk level and ensured safety of the reprocessed devices determined?

Scientific data needs to be accumulated and reviewed by FDA prior to the categorization of medical devices into FDA's proposed risk based categorization scheme. Scientific data needs to be available to determine the risks associated with the specific device and the effects, if any, of the process of reprocessing on the safety and effectiveness of medical devices. The data need to be available prior to the determination of the medical device categorization into an appropriate risk level. Additionally, the data to support the proper classification of devices into risk-based categories needs to be available prior to the implementation of this draft guidance document.

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